IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

[UNDER SEAL], on behalf of the UNITED STATES OF AMERICA, *et al.*, **Plaintiffs/Relator,** **v.** **[UNDER SEAL],** **Defendant.**	**Civil Action No.** **COMPLAINT** **JURY TRIAL DEMANDED** **Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)**

FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

HEALTH CHOICE ALLIES, LLC, on behalf of the UNITED STATES OF AMERICA; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; and STATE OF WASHINGTON,

Plaintiffs/Relator;

v.

GENENTECH INC.

Defendant.

Civil Action No.

COMPLAINT

JURY TRIAL DEMANDED

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

The United States of America ("United States") and the Plaintiff States (collectively, the "Government"), by and through their *qui tam* Relator Health Choice Allies, LLC ("Relator"), allege:

PRELIMINARY STATEMENT

1. This is a civil action brought on behalf of the Government under the Federal False Claims Act, 31 U.S.C. § 3729 – 3733 (the "False Claims Act" or "FCA") and the false claims acts of the respective Plaintiff States[1] to recover treble damages sustained by and civil penalties and restitution owed to the Government as a result of a multi-tiered kickback scheme involving

[1] The state statues are the: (1) California False Claims Act, Cal. Gov't Code §§ 12650 – 12656; (2) Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 – 4-310; (3) Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs Act, Conn. Gen. Stat. Ann. §§ 4-274 – 289; (4) Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211; (5) District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 381.10; (6) Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092; (7) Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 4-168.6; (8) Hawaii False Claims to the State Act, Haw. Rev. Stat. Ann. §§ 661-21 – 31; (9) Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8; (10) Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5.5-18; (11) Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7; (12) Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16; (13) Maryland False Claims Act, Md. Code Ann. Health-Gen. §§ 8-101 – 111; (14) Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O; (15) Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615; (16) Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16; (17) Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 416; (18) Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250; (19) New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 32C-18; (20) New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 14-15; (21) New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 9-14; (22) New York False Claims Act, N.Y. Fin. Law §§ 187 – 194; (23) North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 618; (24) Oklahoma Medicaid False Claims Act, Okl. Stat. Ann. tit. 63, §§ 5053 – 5054; (25) Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 1.1-9; (26) Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 108; (27) Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 – 185; (28) Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132; (29) Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630 – 642; (30) Virginia Fraud Against Tax Payers Act, Va. Code Ann. §§ 8.01-216.1 – 216.19; and (31) Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130.

defendant Genentech Pharmaceuticals ("Genentech").

2. Genentech's unlawful conduct involves its blockbuster product Pegasys (peginterferon alfa-2a) ("Pegasys").

3. To enrich itself at the expense of the Government, Genentech engaged in two intertwined, unlawful marketing schemes for Pegasys.

4. First, Genentech, with material assistance from a number of third-parties, provided in-kind remuneration to Prescribers[2] in the form of free nurse support services in part to induce Prescribers to prescribe Pegasys to their patients.

5. Second, Genentech provided in-kind remuneration to Prescribers in the form of reimbursement support services, saving Prescribers thousands of dollars in administrative expenses. These reimbursement support services were provided in part to induce Prescribers to prescribe Pegasys to their patients.

6. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), expressly prohibits any individual or entity from offering, paying, soliciting, or receiving any "remuneration," which includes "any kickback, bribe, or rebate," to "any person to induce such person" to purchase or recommend a drug or service that is covered by Medicare, Medicaid, or other federal health care programs.[3] Further, the U.S. Department of Health and Human Services ("HHS") has repeatedly warned pharmaceutical companies that they should refrain from engaging in marketing or promotional activities that utilize individuals who are involved in the delivery of healthcare or from providing free services such as billing, nursing, or other staff

[2] As used herein, the term "Prescriber" refers to any physician or Advance Practice Provider authorized to write prescriptions, as well as their employers.

[3] 42 U.S.C. § 1320a-7b.

services.[4]

7. Although Genentech knew that the AKS prohibited it from providing anything of value to Prescribers or from giving kickbacks to promote Pegasys, Genentech disregarded the law, choosing instead to put sales growth and profits before its duties to comply with the law and to ensure patient safety and integrity in the healthcare marketplace.

8. The AKS ensures that the Government pays only for conflict-free medical care and prescriptions that are recommended in the best interests of the patient. A kickback eliminates any sound basis for such assurance because it taints the Prescriber's medical decisions with the Prescriber's financial interests. "The Government does not get what it bargained for when a defendant is paid by [the Government] for services tainted by a kickback." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011) (internal quotations omitted).

9. Due to Genentech's conduct, tens of thousands of prescriptions for Pegasys were written, not based purely on clinical efficacy or patient-specific information, but rather, were tainted by the unlawful, substantial kickbacks Genentech offered Prescribers.

10. Based on Genentech's illegal marketing and promotion schemes, pharmacies have submitted, and continue to submit, claims to federal health care programs, including Medicare and Medicaid, that were tainted by kickbacks, causing these programs to pay billions of dollars in improper reimbursements.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the Government's claims pursuant to 28 U.S.C. §§ 1331 and 1345.

[4] *See, e.g.*, 56 Fed. Reg. 35952-01, 35981 (July 29, 1991); 59 Fed. Reg. 65372-01, 65376 (Dec. 19, 1994).

12. This Court may exercise personal jurisdiction over Genentech because a substantial part of the acts giving rise to the Government's claims occurred within the State of Texas.

13. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) – (c) because Genentech transacts business in this District and/or, in furtherance of its fraudulent kickback schemes, caused to be submitted false claims in this District.

THE PARTIES

14. Genentech is a pharmaceutical company headquartered in South San Francisco, California. In 2009, Genentech was acquired by F. Hoffmann-La Roche Holding AG ("Roche"), a Swiss pharmaceutical company. Genentech markets numerous drugs, one of which is the subject of this complaint: Pegasys.

15. Pegasys (peginterferon alfa-2a) is FDA-approved to treat chronic hepatitis B and chronic hepatitis C. Pegasys is administered by subcutaneous injection.

16. Relator Health Choice Allies, LLC is an affiliate of the National Healthcare Analysis Group ("NHAG"), a research organization based in New Jersey. NHAG representatives have conducted hundreds of interviews of participants in the healthcare marketplace – nurses, sales reps, office managers, administrators, reimbursement support personnel, etc. – to form an understanding of industry practices.

17. Relator brings this action on behalf of the Government pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729 – 3733, and the false claims acts of the respective Plaintiff States.

STATUTORY BACKGROUND

18. In relevant part, the FCA establishes treble damages liability to the United States for any individual or entity that:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or
>
> knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> conspires to commit a violation of [the foregoing paragraphs].[5]

Within the meaning of the FCA, "knowingly" is defined to include reckless disregard and deliberate ignorance. 31 U.S.C. § 3729(b)(1). In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.

19. In relevant part, the AKS, 42 U.S.C. § 1320a-7b, provides as follows:

> (b) Illegal Remunerations.
>
> > (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
> >
> > > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > >
> > > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
> >
> > shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
> >
> > (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

[5] 31 U.S.C. § 3729(a)(1)(A) – (C).

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

20. For purposes of the AKS, "remuneration" includes the transfer of anything of value, whether cash or in-kind consideration, directly or indirectly, covertly or overtly. Importantly, the statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals.

21. The AKS is designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry, and that healthcare professionals remain free of conflicts of interest that could impact treatment decisions.

22. To ensure compliance, every federally-funded health care program requires every Prescriber or supplier to ensure compliance with the provisions of the AKS and other federal laws governing the provision of health care services in the United States.

23. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that "[a]n AKS violation that results in a federal health care payment is a per se false claim under the FCA." *United States ex rel. Lutz v. Bluewave Healthcare Consultants, Inc.*, 853 F.3d 131, 136 (4th Cir. 2017).[6] The PPACA also makes clear that violations of its anti-kickback provisions, like violations of the FCA, may occur

[6] *See also* 42 U.S.C. § 1320a-7b(g).

even if an individual does "not have actual knowledge" or "specific intent to commit a violation."[7]

24. The courts have recognized that claims for reimbursement for medical care tainted by illegal kickbacks are "false" claims within the meaning of the FCA. *See, e.g., Wilkins*, 659 F.3d at 315; *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392-93 (1st Cir. 2011).

25. Knowingly providing kickbacks to Prescribers to induce them to prescribe a drug (or to influence prescriptions) to individuals who seek reimbursement for the drug from a federal Government healthcare program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA.

26. A violation of the AKS constitutes a felony. Any party convicted under the AKS must be excluded from federal health care programs for a term of at least five years.[8]

27. Compliance with the AKS is required for reimbursement of claims from federal health care programs, and claims made in violation of the law are actionable civilly under the FCA. 42 U.S.C. § 1320a-7b(g) (stating, in part, that "a claim that includes items or services resulting from a violation of . . . [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]"); *see also Wilkins*, 659 F.3d at 313 (stating that "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare"). Compliance with the AKS is thus a fundamental and material aspect of what the Government purchases when it pays for medical care for federally insured beneficiaries.

[7] Pub. L. No. 111-148, 124 STAT. 759 § 6402 (adding new section, § 1128J(h)).

[8] 42 U.S.C. § 1320a-7(a).

28. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protect Genentech from liability for the conduct alleged herein.

29. Each of the Plaintiff States has enacted statutes that are parallel to the legislative scheme embodied in the FCA and the AKS.

AFFECTED HEALTH PROGRAMS

30. Generally, when a Prescriber prescribes Pegasys, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal health care program(s) for reimbursement.

31. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal health care program purchases the drug directly rather than reimbursing the pharmacy.

Medicare

32. Medicare is a federal program that provides federally-subsidized health insurance primarily for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq.* ("Medicare Program").

33. Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006.

34. All persons enrolled in Medicare Part A or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, the Center for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D

sponsors") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

35. Generally, after a provider writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM"). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to the CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

36. Payments to a Part D Plan sponsor are "conditioned upon the provision of information to CMS that is necessary" for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage.[9] CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual

[9] 42 C.F.R. § 423.322.

prescription submitted to Medicare under the Part D program.

37. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor's plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low income subsidies.[10] At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages.[11]

38. CMS's payments to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund.[12]

39. In order to receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply

[10] 42 C.F.R. §§ 423.315, 423.329.

[11] 42 C.F.R. § 423.336.

[12] 42 C.F.R. § 423.315(a).

with all applicable federal laws, regulations, and CMS instructions.

40. By statute, all contracts between a Part D Plan sponsor and the HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program.[13]

41. Medicare Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS.[14]

42. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with . . . Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729 *et seq.*), and the Anti-Kickback Statute (section 1128B(b) of the Act)."[15]

43. CMS regulations further require that all subcontracts between Part D Plan sponsors and downstream entities (such as pharmacies and PBMs) contain language obligating the entities in question to comply with all applicable federal laws, regulations, and CMS instructions.[16]

44. A Part D Plan sponsor also is required to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory

[13] 42 U.S.C. § 1395w-112(b)(1).

[14] 42 C.F.R. § 423.505(h)(l).

[15] 42 C.F.R. § 423.505(h)(1).

[16] 42 C.F.R. § 423.505(i)(4)(iv).

provision, entitled "Certification of data that determine payment," provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
>
> (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.
>
> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.87l(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.[17]

45. Compliance with the regulatory requirement that the PDE data submitted to CMS is true, accurate, and complete is a condition of payment under the Medicare Part D program.[18]

46. In accordance with this regulatory requirement, since the Part D program began, Medicare required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"). This Attestation states as follows:

[17] 42 C.F.R. § 423.505(k).

[18] *See id.* at 423.505(k)(1).

> Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

47. All approved Part D Plan sponsors who received payment under Medicare Part D

in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

48. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement."[19]

49. Medicare also enters into agreements with providers to establish the provider's eligibility to participate in the Medicare program. To be eligible for participation in the Medicare program, providers must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the "Certification Statement" that the provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include the following:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

50. Lastly, when submitting a claim using the CMS claim form, the provider certifies

[19] 42 C.F.R. § 423.505(k)(3).

that the claim, whether submitted by the provider or on the provider's behalf, "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute . . . ." Moreover, the provider certifies that the services claimed on the form "were medically necessary and personally furnished by [the provider] or were furnished incident to [the provider's] professional service . . . ."[20]

Medicaid

51. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State Medicaid Program.

52. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims.[21] While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

53. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average.[22] Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total amount

[20] Centers for Medicare & Medicaid Services, CMS 1500 – Health Insurance Claim Form, *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last accessed, Apr. 18, 2018).

[21] 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

[22] 42 U.S.C. § 1396d(b).

expended . . . as medical assistance under the State plan."[23]

54. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies generate funding requests to the state Medicaid programs.

55. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures).[24]

56. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. In fact, providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

57. Furthermore, in many states, Medicaid providers, including physicians and pharmacies, must affirmatively certify compliance with applicable federal and state laws and

[23] 42 U.S.C. § 1396b(a)(l).

[24] 42 C.F.R. § 430.30.

regulations.

58. For example, in New York, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished, [. . .] will be subject to the following certification . . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

59. Similarly, in Texas, "providers (and submitters on behalf of providers) must affirm that they have read, understood, and agree to the certification and terms and conditions of the prior authorization request" before submitting each prior authorization request.[25] By agreeing, the provider and authorization request submitter certify that the information supplied concerning the prior authorization "constitute true, correct, and complete information."[26] Further, the provider and authorization request submitter "understand that payment of claims related to this prior authorization will be from federal and state funds, and that falsifying entries, concealment of a material fact, or pertinent omissions may constitute fraud and may be prosecuted under applicable federal and/or state law."[27] The consequences of omitting information or failing to provide true and accurate information are "termination of the provider's Medicaid enrollment and/or personal exclusion from Texas Medicaid."[28]

60. Additionally, "Texas Medicaid service providers are required to certify

[25] Texas Medicaid Provider Procedures Manual § 5.5.1.2.1 (Dec. 2017), *available at* http://www.tmhp.com/TMHP_File_Library/Provider_Manuals/TMPPM/2017/Dec_2017%20TMPPM.pdf (last accessed, Apr. 16, 2018).

[26] *Id.* § 5.5.1.2.2.

[27] *Id.*

[28] *Id.* § 5.5.1.2.3.

compliance with or agree to various provisions of state and federal laws and regulations."[29]

TRICARE

61. TRICARE is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

62. TRICARE prescription drug benefits are provided through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies, and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies and can submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.

63. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the

[29] *Id.* § 1.6.8.

pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

64. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE/DOD.CHAMPUS Medical Claim-Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.

65. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through

the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by the Defense Logistics Agency ("DLA"). DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals. The PBM then submits a TED record to TRICARE to obtain administrative fees. DLA bills TRICARE directly for drug replenishment costs.

66. Under 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at least 24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

67. Since March 2003, TRICARE has contracted with a pharmacy benefits manager, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

68. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third-party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

69. While some providers enroll in the TRICARE program as network or

participating providers, any provider that is licensed, accredited, and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Providers who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions.[30] TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied.[31] Kickback arrangements are included within the definition of abusive situations that constitute program fraud.[32]

Veterans Administration Health Care

70. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. A VA beneficiary can take a prescription to a VA medical facility, at which point the VA dispenses the medication to the VA beneficiary from its existing inventory. The VA also supports a mail service prescription program as part of its outpatient drug benefit. VA beneficiaries can submit prescriptions to that mail service program, and the VA then dispenses pharmaceuticals purchased by the VA directly to VA beneficiaries. The VA medical system serves approximately four million veterans.

71. The VA purchases the pharmaceuticals that it dispenses at its medical facilities and through its mail service prescription program through its Federal Supply Schedule ("FSS")

[30] 32 C.F.R. § 199.9(a)(4).

[31] *Id.* § 199.9(b).

[32] *Id.* § 199.9(c)(12).

program. Pursuant to Public Law 102-585, pharmaceutical manufacturers are required to enter into national contracts with the VA pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price. A VA facility that requires a supply of a particular medication (including a mail order facility) submits a purchase order to the VA's pharmaceutical prime vendor for distribution of pharmaceuticals.

72. Pursuant to the PPACA, among other things, all claims to Government reimbursement programs resulting from a violation of the AKS are also a violation of the FCA.

73. Moreover, the statutes and regulations set forth above concerning Medicare, Medicaid, TRICARE, and Veterans Administration Health Care, when viewed together, state that healthcare providers must comply with the AKS in order for claims they cause to be submitted to these programs to be reimbursed.

74. Here, the claims submitted for Genentech's drug Pegasys violated the AKS because they stemmed from prescriptions that were tainted by kickbacks, and the participants in the scheme knew that the claims for reimbursement would be submitted to the above programs. As such, and as more fully discussed below, the Prescribers, expressly and impliedly, falsely certified compliance with the conditions of payment for, at least, Medicare, Medicaid, TRICARE, and Veterans Administration Health Care.

75. In addition to falsely certifying compliance with the AKS, the Prescribers also falsely certified compliance with contractual provisions that were conditions for payment.

RELATOR'S INVESTIGATION

76. To unmask Genentech's unlawful conduct, Relator and its representatives interviewed numerous individuals with knowledge of the scheme.

- Confidential Interviewee #1 ("CI-1") was employed by Genentech as a sales rep for the Genentech drug Pegasys from May 2004 through March 2015. His

territory included the District of Columbia and the states of Virginia and Maryland.

- Confidential Interviewee #2 ("CI-2") was employed by Genentech as an HCV senior clinical specialist for the Genentech drug Pegasys from 2004 through 2012.
- Confidential Interviewee #3 ("CI-3") was employed by a third-party as a nurse educator for the Genentech drug Pegasys from February 2015 through June 2016. Her territory spanned the state of Alabama.
- Confidential Interviewee #4 ("CI-4") was employed as a nurse educator for the Genentech drug Pegasys from October 2005 through October 2012. Her territory spanned the entire Midwest of the United States.
- Confidential Interviewee #5 ("CI-5") was a case manager on the reimbursement team for the Genentech drug Pegasys from 2002 through 2014.
- Confidential Interviewee #6 ("CI-6") was employed by a third-party as a nurse educator for the Genentech drug Pegasys from February 2010 through December 2014. Her territory included the northern part of the state of California.

THE FRAUDULENT SCHEMES

77. Based on Relator's investigation, there is overwhelming evidence that Genentech engaged in a complex, multi-part scheme that involved the payment of kickbacks to Prescribers for the purpose of increasing prescriptions of Pegasys.

78. In the first scheme, Genentech, with assistance from third-parties, provided free nurse support services to Prescribers in part to induce them to prescribe Pegasys to their patients.

79. In the second scheme, Genentech provided in-kind remuneration in the form of reimbursement support services, saving Prescribers thousands of dollars in administrative

expenses, in part to induce Prescribers to recommend Genentech's drug Pegasys.

Scheme One: Providing Free Nurse Support Services to Prescribers

80. In the first scheme, Genentech offered free nurse education and patient management services ("Nurse Support Services" or "NSS") to Prescribers in exchange for those Prescribers recommending Pegasys over competitor drugs.

81. Most Prescribers typically allocate between 10 and 15 minutes to see routine patients. Patients affected by chronic diseases, however, often require extra office time and resources. For this reason, many Prescribers rely on nurse educators. Nurse educators typically cost $50,000 to $100,000 in annual salary, or an average hourly wage of $40.00 per hour.

82. Seeking a competitive advantage over competitors, Genentech attempted to meet the needs and challenges that Prescribers face in managing their practice and patients. Accordingly, Genentech developed a marketing strategy that involves furnishing Nurse Support Services to Prescribers to induce them to choose Pegasys over competing drugs. Genentech's NSS include: (i) assisting Prescribers to increase practice efficiency; (ii) training Prescribers' staff on patient care; (iii) eliminating the expense to Prescribers of having to educate patients; and (iv) being on call to answer patients' questions. Genentech provided these Nurse Support Services through nurse educators supplied by third-parties – free of charge. Of course, in typical *quid pro quo* fashion, to obtain these NSS, Prescribers would in turn have to prescribe Genentech's drug Pegasys.

83. It is in this manner that, rather than promoting and marketing Genentech drugs based upon patient outcomes and efficacy, Genentech, with the assistance of third-parties, adds incentives for Prescribers to recommend Pegasys over competing drugs. The Confidential Interviewees confirm that the NSS saved Prescribers (and their staff) time, money, and resources and "eliminate[d] an expense that the physician would have otherwise incurred" – the very type

of conduct that the Office of the Inspector General ("OIG") has flagged as suspect.[33] Such in-kind remuneration, given to induce a recommendation for Pegasys, is an unlawful kickback under the AKS and justifies action under the FCA.

84. The Confidential Interviewees confirm that Genentech sales reps and nurse educators are trained by Genentech to use NSS as a selling tool to induce Prescribers to prescribe Genentech products such as Pegasys. For example, Genentech sales reps and nurse educators are trained to encourage Prescribers to "off-load" their patients to the nurse educators. The nurse educators then take over the day-to-day management and care of those patients, but only if those patients are prescribed Genentech's drugs, in this case, Pegasys. Additionally, the time and cost-savings Prescribers would realize by availing themselves of the Nurse Support Services are emphasized during sales calls.

85. For example, CI-1 (sales rep) explained: "if a nurse educator was offered as a resource where they actually take the burden out of the hands of the clinician, in terms of properly educating the patients on the therapy[, that] frees up time for the clinician to actually focus on prescribing the drug instead of trying to manage [patients]." As such, the NSS program "increases the likelihood" that a Prescriber will recommend Genentech products.

86. CI-2 (sales rep) agreed that the NSS program resulted in "time savings for the office staff," which, in turn, "made it much easier for the offices to prescribe" Genentech products.

---

[33] *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, Dep't of Health & Human Servs., 68 Fed. Reg. 23731-01, 23737 (May 5, 2003), *available at* https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf (noting that, if "services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (*i.e.*, have independent value to the physician) . . . the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer").

87. CI-3 (nurse educator) "strongly agree[d]" that Genentech's offering of nurse educators resulted in a tangible benefit to Prescribers. CI-3 explained that the program "keeps the patients out of the doctor's offices, which keeps the doctor's offices less busy with stuff." This "saves providers time." (CI-3).

88. CI-4 (nurse educator) similarly agreed that the Genentech-trained nurses "made the [Prescribers'] job easier, there's no doubt about it. We made their job easier in working with these Hepatitis-C patients because they're very needy, and very demanding, and do not have the highest educational level. And, we just provided support that the physician then did not have to be there for."

89. In sum, Genentech has unlawfully furnished to Prescribers the services of these nurses to work with the Prescribers' patients. Genentech intended for these Nurse Support Services to act as an inducement to Prescribers in return for recommending Genentech's drugs to patients. When Prescribers received the benefits of the nurses' service, Genentech "eliminate[d] an expense that [the Prescribers] would have otherwise incurred"[34] if they had employed the nurse or provided the services themselves. Genentech thus violated the AKS by offering unlawful, in-kind remuneration in exchange for increased prescriptions for Genentech's drug Pegasys.

90. Not only does Genentech's provision of free NSS violate the AKS, but it also creates a disturbing conflict of interest for the nurses. This conflict can harm patients and vastly increase pharmaceutical spending.

91. In a normal nurse-to-patient relationship, the nurse has no allegiance to or affiliation with any drug or drug company and is able to make a decision based solely upon the

[34] *OIG Compliance Program Guidance for Pharmaceutical Manufacturers,* Dep't of Health & Human Servs., 68 Fed. Reg. at 23737.

best interests of the patient. During recent years, scholars have raised concerns that increased promotional spending by pharmaceutical companies on nurses (mostly in the form of small gifts, dinners, or drug samples) is creating a serious conflict, and have suggested that a ban or strong limitation on such conduct is needed to protect patients.[35] The conflict created by Genentech's use of these nurses, which extends *far* beyond simple gifts and drug samples, is much greater. Here, the nurses are actually in contract with Genentech through third-parties. Genentech trains and directs these nurses to increase sales. Thus, the nurses have an inherent interest in the success of the Genentech drugs, which creates a conflict with their duty of care to patients. The nurses may consciously or subconsciously recommend Genentech drugs despite cheaper alternatives or more effective treatments, to the detriment of a patient.[36]

92. The conflict of interest manifests in two related situations, continuity of care[37] and medication adherence. A Prescriber's decision to keep a patient on a certain drug or switch to a competing drug should be based on patient outcomes. However, since the nurses' interests are closely aligned with Genentech's, the nurses' independence is compromised and they will promote Genentech's drugs when other drugs may be more appropriate. This conduct not only violates the AKS, but raises ethical and patient safety concerns for the nursing profession.

---

[35] Nancy J. Crigger, *Pharmaceutical Promotions and Conflict of Interest in Nurse Practitioner's Decision Making: The Undiscovered Country*, 17 J. Am. Academy of Nurse Practitioners 207-12 (May 27, 2005).

[36] Judith A. Erlen, *Conflict of Interest – Nurses at Risk!*, 27 Orthopaedic Nursing 135-39 (Mar. – Apr. 2008). Erlen argues that a nurse simply accepting small gifts (such as notepads and promotional items) or listening to a marketing pitch is enough to cloud their judgment and create a conflict of interest. *Id.* at 137. This is a far cry from the situation highlighted here where the nurse *is indirectly employed* by the drug manufacturer.

[37] Continuity of care is concerned with quality of care over time. It is the process by which the patient and his/her Prescriber-led care team are cooperatively involved in ongoing health care management toward the shared goal of high quality, cost-effective medical care.

Scheme Two: Reimbursement Support Services as Inducement

93. To induce recommendations of Pegasys over competing drugs, Genentech sales reps are trained to offer a second type of kickback: free reimbursement support services for Prescribers who write prescriptions for Pegasys. This remuneration is a tangible, in-kind benefit that greatly reduces, and in some instances eliminates, Prescribers' administrative costs related to prescribing Pegasys. Genentech refers to this remuneration as coverage determination and/or reimbursement support services, but in practice, the services are intended to induce Prescribers to choose Genentech's drug Pegasys over a competitor's drugs.

94. Over the past few years, in an effort to boost sales of Genentech products, Genentech offered free coverage determination and reimbursement support for prescriptions of Pegasys. The services include activities like patient insurance benefit verification services, patient prior authorization services, and coverage appeals (collectively, "Reimbursement Support Services" or "RSS").

95. Genentech's sales reps marketed the RSS in order to increase the likelihood that Prescribers would prescribe Pegasys. Put simply, in exchange for prescribing Pegasys, Genentech assumes and underwrites the Prescribers' administrative responsibilities and costs associated with starting a patient on Pegasys. The more a Prescriber prescribes Pegasys as a percentage of its overall prescription volume, the greater the Prescriber's savings, as time and money spent on RSS for Pegasys is now handled by Genentech. As detailed below, Genentech's Reimbursement Support Services are the "carrot" (*i.e.*, remuneration) dangled to induce Prescribers to recommend Genentech's drugs to their patients.

96. RSS have a tangible value to Prescribers because these services reduce, and in some instances eliminate, the administrative costs associated with prescribing drugs. These services also help increase profitability, particularly for office-based Prescribers, who derive

most of their revenue from billing 15-, 30-, and 45-minute units of service provided to patients during office visits.

97. The technical term for an office visit is evaluation and management services ("E/M"). In 2012, the most commonly billed Medicare provider service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. Medicare pays over $11 billion each year for E/M services alone. Medicaid and private insurers also pay billions each year.

98. When an office-based Prescriber receives payment for an E/M service, the payment is intended to compensate the Prescriber for the actual medical care given *and* administrative tasks associated with that patient's care. These tasks include conducting a patient's prescription drug insurance "benefit verification," determining if the drug is on the formulary lists and tiers, seeking a coverage determination, determining co-pays and deductibles, conducting telephone calls to patients, responding to patient complaints, returning messages and faxes, handling prescription refill requests, and, where necessary, obtaining "prior authorizations"[38] and managing the resulting paper trail.[39] Despite these enormous

[38] A study of 12 primary care practices published in the *Journal of the American Board of Family Medicine* estimated the mean annual projected cost per full-time equivalent physician for prior authorization activities between $2,161 and $3,430. The study's authors concluded that "preauthorization is a measurable burden on physician and staff time." *See* Christopher P. Morley, et al., *The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies*, 26 J. Am. Bd. Fam. Med. 93-95 (Jan.-Feb. 2013).

[39] In 2006, primary care providers spent a mean of 1.1 hours per week on authorizations, primary care nursing staffs spent 13.1 hours per week, and primary care clerical staff spent 5.6 hours per week, according to a 2009 study published in *Health Affairs*. The study estimated that the overall cost to the healthcare system of all practice interactions with health plans, including authorizations, was between $23 billion and $31 billion annually. *See* Lawrence P. Casalino, *et al.*, *What Does It Cost Physician Practices to Interact with Health Insurance Plans?*, 28 Health Affairs 533-543 (May 14, 2009), *available at* http://content.healthaffairs.org/content/28/4/w533.full.

administrative costs and expenses,[40] office-based Prescribers are not permitted, under federal or state regulations, to directly charge patients a fee for any of these services.[41] Instead, Prescribers get paid for these services indirectly through the E/M unit charge.

99. Since a Prescriber's E/M reimbursement for each office visit is fixed per unit, Prescribers are continuously seeking ways to combat overhead costs and reduce expenses in order to earn more profit from each E/M unit billed. One way to do so is to reduce the administrative costs associated with prescribing drugs. If a Prescriber can reduce this cost, each E/M unit will be more profitable. These economics have a direct impact on a Prescriber's prescribing behavior. Prescribers are less likely to prescribe a drug that imposes an undue burden on support staff because doing so would mean a decrease in profitability resulting from the need to hire more staff or reduce the number of patients that can be seen in a day. Conversely, a Prescriber is much more likely to prescribe a drug if it can be prescribed with little or no administrative burden. Thus, the Prescriber's relative cost and burden in prescribing one company's drug when compared to another company's drug can directly influence which drug a

[40] A 2011 study published in *Health Affairs* found that providers spend an annual average of nearly $83,000 of overhead staff time and costs associated with coverage plan issues. With approximately 835,000 physicians practicing in the nation, this translates to over $69 billion annually. *See* Dante Morra, *et al., US Physician Practices Versus Canadian; Spending Nearly Four Times as Much Money Interacting with Payers*, 30 Health Affairs 1443-1450 (Aug. 3, 2011), *available at* http://content.healthaffairs.org/content/30/8/1443.full.pdf+html.

[41] For example, in Texas, "[p]roviders must certify that no charges beyond reimbursement paid under Texas Medicaid for covered services have been, or will be, billed to an eligible client." The Texas Medicaid Provider Procedures Manual makes clear to providers that "Federal regulations prohibit providers from charging clients a fee for completing or filing Medicaid claim forms" and notes that the "cost of claims filing is part of the usual and customary rate for doing business." Further, providers cannot charge "Texas Medicaid clients, their family, or the nursing facility for telephone calls, telephone consultations, or signing forms." Texas Medicaid Provider Procedures Manual § 1.6.9 (Dec. 2017), *available at* http://www.tmhp.com/TMHP_File_Library/Provider_Manuals/TMPPM/2017/Dec_2017%20TMPPM.pdf (last accessed, Apr. 16, 2018).

Prescriber will recommend to a patient.

100. The economics of this are not lost on pharmaceutical manufacturers like Genentech. As such, Genentech developed Reimbursement Support Services that are marketed to Prescribers to increase the likelihood that Prescribers will choose to recommend Genentech's drug Pegasys. While these services cost millions of dollars to provide, Genentech readily incurs this expense, knowing that these services are a powerful inducement to Prescribers to recommend Pegasys over competitor drugs.

101. Because many drugs are expensive, most, if not all patients, cannot afford therapy unless it is covered by insurance. For example, Pegasys costs upwards of $30,000 per year. As a result, successfully starting patients on a drug therapy typically requires an initial determination to verify whether the patient has adequate prescription drug coverage. This step is called "benefit verification." For most Prescribers, the verification of a patient is performed by staff, and it is a time-consuming task. It can take multiple calls lasting up to and sometimes over an hour just to determine the nature and extent of the patient's coverage. However, if the Prescriber recommends Pegasys, the verification task for the Genentech drug is handled in-house by Genentech's employees, rather than the Prescriber's staff.

102. Genentech's reimbursement support team receives electronic and fax requests from Prescribers to perform benefit verifications for their patients. These requests are immediately assigned to a Genentech reimbursement support employee who has training, education, and experience in determining patients' prescription drug benefits. First, the reimbursement support specialist verifies the source of the patient's primary and secondary insurance benefits (*i.e.*, private insurance, Medicare, Tricare, and/or Medicaid). Next, the reimbursement support specialist contacts the insurer to verify the nature and extent of the

patient's drug benefit coverage. In the case of Medicare or Medicaid, this is called a "coverage determination." For Medicare patients, coverage determinations tend to be particularly cumbersome and time consuming given the complexity of many Part D plans.

103. In addition to verifications and coverage determinations, Genentech also provides prior authorization services. Many insurance carriers require a Prescriber to obtain a prior authorization before prescribing certain medications. Further, if a medication receives an authorization, that authorization may only be valid for a limited time, such as one year or one month. After that, the Prescriber must start the prior authorization process over again. The cumbersome process often causes Prescribers to choose less expensive medications that do not require a prior authorization. Indeed, Part D carriers use the prior authorization process as a means to contain costs associated with expensive medications, like Genentech's drug Pegasys. Thus, if a Prescriber wants to recommend expensive drugs, the Part D carriers require the Prescriber to go through the administrative process and make the case for prescribing the drug over a less expensive option. However, Genentech has relieved Prescribers of that burden in order to induce them to prescribe Pegasys over competing medications.

104. Genentech also offers a service to appeal authorization and coverage denials. If a patient's carrier denies coverage for Genentech's products or denies the prior authorization request, Genentech takes steps to reverse the adverse determination.

105. Prior authorizations and coverage appeals take time and experienced personnel. The process of obtaining a prior authorization and/or appealing a denial requires direct input from the Prescriber regarding the patient's medical history, clinical and laboratory findings, and other information to establish the patient's medical necessity for a particular drug. The Prescriber and his or her staff must also develop specialized knowledge about each carrier's

unique prior authorization and coverage criteria.

106. The Confidential Interviewees confirm that Genentech's reimbursement support team directly assists Prescribers who prescribe Genentech drugs. The Genentech sales reps market these services to Prescribers as being free of charge, but only to those Prescribers that prescribe Genentech products.

107. These Reimbursement Support Services have real value to Prescribers. Without them, Prescribers would have to use their own staff and resources or outsource the RSS to a private vendor. Importantly, the payer-Prescriber contracts with Medicare, Medicaid, and private insurers prohibit the Prescriber from charging patients a fee for these administrative services separate from the E/M unit charge. Genentech offers Prescribers a means to "outsource" this function without any direct or indirect cost to the Prescriber, but only if the Prescriber chooses to recommend Pegasys to patients. By offering these in-kind services (*i.e.*, a tangible benefit that saves time and money) as a means to induce Prescribers to recommend Genentech products, Genentech violated the AKS and should be held accountable under the FCA.

108. While pitching Prescribers, Genentech sales reps emphasized that, if the Prescribers recommended Pegasys to their patients, Genentech would provide the services and resources of a full reimbursement support team to manage the administrative tasks associated with prescribing the Genentech products. Genentech sales reps further emphasized that the cost and expenses normally associated with managing a patient's prescription would be shifted to Genentech, thereby increasing the Prescriber's bottom line.

109. This value proposition is a powerful tool in the hands of Genentech's sales reps and is used to induce Prescribers to recommend Genentech drugs.

110. As CI-1 (sales rep) explained, "it comes down to time. If it takes a doctor five minutes to write out a prescription and send that over to whatever reimbursement or specialty support as opposed to spending the time on the phone with them for an hour to have one prescription, I think that will lead them to write more prescriptions because it will make their job that much more easier."

111. CI-5 (case manager for Genentech's reimbursement team) agreed: "[I]t helps their [(Prescribers')] office staff not to have to be on hold with the payers, or helps save time with their office staff when they could be doing other things instead of paying your office staff to be on hold with the insurance companies."

112. Indeed, to take advantage of these dynamics, Genentech built up "a whole arm of a company that does [Reimbursement Support Services]." (CI-6).

THE BREADTH OF GENENTECH'S KICKBACK SCHEME

113. The evidence uncovered during Relator's investigation reveals that Genentech has engaged in extensive kickback schemes.

114. The scheme encompasses every Prescriber that, since at least 2002, received, directly or indirectly, free Nurse Support Services that were paid for by Genentech.

115. The scheme encompasses every Prescriber that, since at least 2002, received Reimbursement Support Services for Genentech's drug Pegasys from Genentech.

116. Genentech profited from the illegal schemes described in this Complaint, and federal health care programs, including Medicare, Medicaid, TRICARE, and Veteran Administration Healthcare, were made to bear the costs.

117. Since at least 2002, Genentech has knowingly caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries and others to submit millions of dollars in claims to Government

programs for Genentech's drug Pegasys. Those false claims have caused the Government to disburse billions of dollars in reimbursements that were tainted by kickbacks and should not have been paid.

118. Genentech employed the two schemes detailed above across the nation, and Pegasys was marketed, prescribed, and sold nationwide. Claims for Pegasys were submitted to federal and state healthcare programs, including Medicare and Medicaid, in most, if not all states.

COUNT 1 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
PRESENTING FALSE CLAIMS FOR PAYMENT (31 U.S.C. § 3729(a)(1)(A))

119. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

120. Relator seeks relief against Genentech under Section 3729(a)(1)(A) of the FCA, 31 U.S.C. § 3729(a)(1)(A).

121. As a result of Genentech offering or paying, and Prescribers, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend the purchasing or ordering of Genentech's drug Pegasys in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Genentech caused false and fraudulent claims for payment to be presented to federal health care programs.

122. Accordingly, Genentech knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

123. By reason of the false or fraudulent claims that Genentech knowingly caused to be presented to federal health care programs, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

**COUNT 2 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
USE OF FALSE STATEMENTS (31 U.S.C. § 3729(a)(1)(B))**

124. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

125. Relator seeks relief against Genentech under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B).

126. As a result of Genentech offering or paying, and Prescribers and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend purchasing or ordering Genentech's drug Pegasys in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Genentech knowingly caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others to make false records or statements that were material to getting false or fraudulent claims paid by federal health care programs.

127. More specifically, the pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others, falsely certified, and/or represented that the reimbursements they sought for Genentech's drug Pegasys were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the AKS. Those false certifications, statements, or representations caused federal health care programs to pay out sums that would not have been paid if those programs had been made aware of the falsity of the certifications, statements, or representations.

128. Accordingly, Genentech caused the use of false records or statements material to false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(B).

129. By reason of these false records or statements, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to treble damages plus a monetary civil penalty for each false record or statement.

**COUNT 3 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
CONSPIRING TO VIOLATE THE FALSE CLAIMS ACT (31 U.S.C. § 3729(a)(1)(C))**

130. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

131. Relator seeks relief against Genentech under Section 3729(a)(1)(C) of the FCA, 31 U.S.C. § 3729(a)(1)(C).

132. As set forth above, Genentech conspired with third-parties that supplied nurse educators, Prescribers, and other health care professionals to offer or pay kickbacks in exchange for, or to induce them to purchase, order, or recommend the purchasing or ordering of Genentech's drug Pegasys in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), thereby causing false and fraudulent claims to be presented to federal health care programs seeking reimbursement for Genentech's drug Pegasys dispensed in connection with the kickback scheme.

133. Accordingly, Genentech conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729(a)(1)(C).

134. By reason of Genentech's conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

**COUNT 4 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT,
CAL. GOV'T CODE §§ 12650 – 12656**

135. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 – 12656. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

136. Genentech violated the California False Claims Act by engaging in the fraudulent

and illegal practices described herein, including knowingly causing false claims to be presented to the State of California as described herein.

137. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

138. The State of California, unaware of the false or fraudulent nature of these claims, paid such claims which the State of California would not otherwise have paid.

139. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

COUNT 5 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT,
COL. REV. STAT. ANN. §§ 25.5-4-303.5 – 25.5-4-310

140. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 – 25.5-4-310. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

141. Genentech violated the Colorado Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado, as described herein.

142. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

143. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Colorado would not otherwise have paid.

144. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 6 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS AND OTHER PROHIBITED ACTS UNDER STATE-ADMINISTERED HEALTH OR HUMAN SERVICES ACT ("CONNECTICUT FALSE CLAIMS ACT"),
CONN. GEN. STAT. ANN. §§ 4-274 – 4-289**

145. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. Ann. §§ 4-274 – 4-289. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

146. Genentech violated the Connecticut False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut, as described herein.

147. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

148. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Connecticut would not otherwise have paid.

149. By reason of these payments, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 7 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT,
DEL. C. ANN. TIT. 6, §§ 1201 – 1211**

150. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

151. Genentech violated the Delaware False Claims and Reporting Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware, as described herein.

152. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

153. The State of Delaware, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Delaware would not otherwise have paid.

154. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 8 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE DISTRICT OF COLUMBIA
MEDICAID FRAUD ENFORCEMENT AND
RECOVERY AMENDMENT ACT OF 2012,
D.C. CODE ANN. §§ 2-381.01 – 2-381.10**

155. This is a claim for treble damages and civil penalties under District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 2-381.10. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

156. Genentech violated the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012 by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the District of Columbia, as described herein.

157. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

158. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims which the District of Columbia would not otherwise have paid.

159. By reason of these payments, the District of Columbia has been damaged, and

continues to be damaged, in a substantial amount.

**COUNT 9 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE FLORIDA FALSE CLAIMS ACT,
FLA. STAT. ANN. §§ 68.081 – 68.092**

160. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

161. Genentech violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

162. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

163. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Florida would not otherwise have paid.

164. By reason of these payments, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 10 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE GEORGIA FALSE MEDICAID CLAIMS ACT,
GA. CODE ANN. §§ 49-4-168 – 49-4-168.6**

165. This is a claim for treble damages and civil penalties under Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 49-4-168.6. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

166. Defendant violated the Georgia False Medicaid Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia, as described herein.

167. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

168. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Georgia would not otherwise have paid.

169. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 11 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE HAWAII FALSE CLAIMS TO THE STATE ACT,
HAW. REV. STAT. §§ 661-21 – 661-31

170. This is a claim for treble damages and civil penalties under the Hawaii False Claims to the State Act, Haw. Rev. Stat. §§ 661-21 – 661-31. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

171. Genentech violated the Hawaii False Claims to the State Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawaii, as described herein.

172. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii.

173. The State of Hawaii, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Hawaii would not otherwise have paid.

174. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 12 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE ILLINOIS FALSE CLAIMS ACT,
740 ILL. COMP. STAT. ANN. §§ 175/1 – 175/8**

175. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

176. Genentech violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois, as described herein.

177. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

178. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Illinois would not otherwise have paid.

179. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 13 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE INDIANA FALSE CLAIMS
AND WHISTLEBLOWER PROTECTION ACT,
IND. CODE ANN. §§ 5-11-5.5-1 – 5-11-5.5-18**

180. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblowers Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

181. Genentech violated the Indiana False Claims and Whistleblowers Protection Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Indiana, as described herein.

182. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

183. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Indiana would not otherwise have paid.

184. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 14 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE IOWA FALSE CLAIMS ACT,
IOWA CODE ANN. §§ 685.1 – 685.7

185. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

186. Genentech violated the Iowa False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Iowa, as described herein.

187. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Iowa.

188. The State of Iowa, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Iowa would not otherwise have paid.

189. By reason of these payments, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 15 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE LOUISIANA
MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW,
LA. STAT. ANN. §§ 437.1 – 440.16**

190. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

191. Genentech violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana, as described herein.

192. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana.

193. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Louisiana would not otherwise have paid.

194. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 16 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE MARYLAND FALSE HEALTH CLAIMS ACT,
MD. CODE ANN., HEALTH-GEN. §§ 8-101 – 8-111**

195. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act, Md. Code Ann., Health-General §§ 8-101 – 8-111. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

196. Genentech violated the Maryland False Health Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Maryland, as described herein.

197. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Maryland.

198. The State of Maryland, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Maryland would not otherwise have paid.

199. By reason of these payments, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount.

COUNT 17 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE MASSACHUSETTS FALSE CLAIMS LAW,
MASS. GEN. LAWS ANN. CH. 12, §§ 5A – 5O

200. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

201. Genentech violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Massachusetts, as described herein.

202. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Massachusetts.

203. The Commonwealth of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Massachusetts would not otherwise have paid.

204. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 18 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIM ACT,
MICH. COMP. LAWS ANN. §§ 400.601 – 400.615**

205. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

206. Genentech violated the Michigan Medicaid False Claim Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Michigan, as described herein.

207. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

208. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Michigan would not otherwise have paid.

209. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 19 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT,
MINN. STAT. ANN. §§ 15C.01 – 15C.16**

210. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

211. Genentech violated the Minnesota False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Minnesota, as described herein.

212. As a result of the misconduct alleged herein, Genentech knowingly made, used, or

caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

213. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Minnesota would not otherwise have paid.

214. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

COUNT 20 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT,
MONT. CODE ANN. §§ 17-8-401 – 17-8-416

215. This is a claim for treble damages and civil penalties under Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 17-8-416. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

216. Genentech violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Montana, as described herein.

217. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

218. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Montana would not otherwise have paid.

219. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 21 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE NEVADA SUBMISSION
OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT,
NEV. REV. STAT. ANN. §§ 357.010 – 357.250**

220. This is a claim for treble damages and civil penalties under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

221. Genentech violated the Nevada Submission of False Claims to State or Local Government Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada, as described herein.

222. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

223. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Nevada would not otherwise have paid.

224. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 22 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT,
N.J. STAT. ANN. §§ 2A:32C-1 – 2A:32C-18**

225. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 2A:32C-18. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

226. Genentech violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be

presented to the State of New Jersey, as described herein.

227. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

228. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Jersey would not otherwise have paid.

229. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount.

COUNT 23 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE NEW MEXICO FRAUD AGAINST TAXPAYERS ACT,
N.M. STAT. ANN. §§ 44-9-1 – 44-9-14,
AND THE NEW MEXICO MEDICAID FALSE CLAIMS ACT,
N.M. STAT. ANN. §§ 27-14-1 – 27-14-15

230. This is a claim for treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 44-9-14, and the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 27-14-15. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

231. Genentech violated the New Mexico Fraud Against Taxpayers Act and the New Mexico Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

232. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

233. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

234. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

COUNT 24 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT,
N.Y. FIN. LAW §§ 187 – 194

235. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. Fin. Law §§ 187 – 194. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

236. Genentech violated the New York False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York, as described herein.

237. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

238. The State of New York, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New York would not otherwise have paid.

239. By reason of these payments, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

COUNT 25 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT,
N.C. GEN. STAT. ANN. §§ 1-605 – 1-618

240. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 1-618. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

241. Genentech violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be

presented to the State of North Carolina, as described herein.

242. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

243. The State of North Carolina, unaware of the false or fraudulent nature of these claims, paid such claims which the State of North Carolina would not otherwise have paid.

244. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

COUNT 26 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT,
OKL. STAT. ANN. TIT. 63, §§ 5053 – 5054

245. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okl. Stat. tit. 63, §§ 5053 – 5054. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

246. Genentech violated the Oklahoma Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma, as described herein.

247. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

248. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Oklahoma would not otherwise have paid.

249. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 27 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE RHODE ISLAND STATE FALSE CLAIMS ACT,
R.I. GEN. LAWS ANN. §§ 9-1.1-1 – 9-1.1-9**

250. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9-1.1-9. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

251. Genentech violated the Rhode Island State False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island, as described herein.

252. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

253. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Rhode Island would not otherwise have paid.

254. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 28 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE TENNESSEE FALSE CLAIMS ACT,
TENN. CODE ANN. §§ 4-18-101 – 4-18-108
AND THE TENNESSEE MEDICAID FALSE CLAIMS ACT,
TENN. CODE. ANN. §§ 71-5-181 – 71-5-185**

255. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 4-18-108, and the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 71-5-181 – 71-5-185. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

256. Genentech violated the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including

knowingly causing false claims to be presented to the State of Tennessee, as described herein.

257. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

258. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

259. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

COUNT 29 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW,
TEX. HUM. RES. CODE ANN. §§ 36.001 – 36.132

260. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

261. Genentech violated the Texas Medicaid Fraud Prevention Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas, as described herein.

262. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

263. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Texas would not otherwise have paid.

264. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 30 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE VERMONT FALSE CLAIMS ACT,
VT. STAT. ANN. TIT. 32, §§ 630 – 642**

265. This is a claim for treble damages and civil penalties under the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630 – 642. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

266. Genentech violated the Vermont False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State as Vermont, as described herein.

267. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Vermont.

268. The State of Vermont, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Vermont would not otherwise have paid.

269. By reason of these payments, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 31 – AGAINST GENENTECH,
FOR VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT,
VA. CODE ANN. §§ 8.01-216.1 – 8.01-216.19**

270. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 – 8.01-216.19. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

271. Genentech violated the Virginia Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Virginia, as described herein.

272. As a result of the misconduct alleged herein, Genentech knowingly made, used, or

caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Commonwealth of Virginia.

273. The Commonwealth of Virginia, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Virginia would not otherwise have paid.

274. By reason of these payments, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 32 – AGAINST GENENTECH, FOR VIOLATIONS OF THE WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT, WASH. REV. CODE ANN. §§ 74.66.005 – 74.66.130

275. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

276. Genentech violated the Washington Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Washington, as described herein.

277. As a result of the misconduct alleged herein, Genentech knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Washington.

278. The State of Washington, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Washington would not otherwise have paid.

279. By reason of these payments, the State of Washington has been damaged, and continues to be damaged, in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Genentech as follows:

(a) treble the Government's damages in an amount determined at trial, plus the maximum statutorily-allowed penalty for each false claim submitted in violation of the FCA or State statute set forth above;

(b) the applicable administrative civil penalties for each violation of the AKS and State-equivalent statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of that amount was offered, paid or received for a lawful purpose;

(c) an award of costs and the maximum Relator award allowed pursuant to the FCA and State statutes set forth above; and

(d) such further relief as is proper.

Dated: April 19, 2018

Respectfully submitted,

/s/ Sam Baxter
Samuel F. Baxter (co-lead counsel)
sbaxter@mckoolsmith.com
Jennifer L. Truelove
jtruelove@mckoolsmith.com
MCKOOL SMITH P.C.
104 East Houston, Suite 300
Marshall, Texas 75670
(903) 923-9000
Fax: (903) 923-9099

Eric B. Halper
ehalper@mckoolsmith.com
Radu A. Lelutiu
rlelutiu@mckoolsmith.com
Dana E. Vallera
dvallera@mckoolsmith.com
Karla Y. Valenzuela
kvalenzuela@mckoolsmith.com
MCKOOL SMITH P.C.
One Bryant Park, 47th Floor
New York, New York 10036
(212) 402-9400
Fax: (212) 402-9444

ATTORNEYS FOR RELATOR